

**RESPONSE UNDER 37 C.F.R. 1.116
EXPEDITED PROCEDURE
EXAMINING GROUP 3743**

Rejections Under 35 U.S.C. § 112

Claims 3, 6, 7, and 8 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Specifically, the Office Action alleges that the definition of “oscillation” outlined in the last Response does not correspond to the use of this term as recited in claim 3. Also, claim 6-8 are alleged to attempt to broaden the range of claim 18 in a dependent claim. Claim 18 has been amended as further described below to further recite the oscillatory motion of the biopharmaceutical solution. Also, the language regarding the frequency of the oscillatory motion has been deleted from claim 18 and thus claims 6-8 which further recite the range of oscillation do not conflict therewith. Thus, it is believed these objections are overcome.

Claims 2-3, 6-9, and 18 also stand rejected under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the specification such that one of ordinary skill in the art at the time the application was filed had possession of the claimed invention. Specifically, the Office Action objects to the specific frequency recited in claim 18. This frequency range has been removed from claim 18 and thus this rejection is believed to be overcome.

Rejections Under 35 U.S.C. § 103

Claims 2, 3, 6-9, and 18 have been rejected under 35 U.S.C. § 103(a) as being obvious over the 1992 Wisniewski and Wu article. Specifically, page 34 is alleged to teach a shaker platform which oscillates in the range recited in claim 18 as submitted in the Response filed June 19, 2002.

Claim 18 has been amended to recite a method for thawing a frozen biopharmaceutical solution which includes heating the biopharmaceutical solution, when at least a portion of the biopharmaceutical solution is frozen. The heating is performed using a

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heating element coupled to a container which contains the biopharmaceutical solution. Oscillatory motion is induced to the biopharmaceutical solution to thaw the at least a portion of the biopharmaceutical solution using an oscillatory driver adapted to be coupled to the biopharmaceutical solution. The driver inducing the oscillatory motion rolls the container from a first position to a second position and the driver rolls the container a distance from the second position toward the first position.

As described in the previous Response, the Wisniewski and Wu article teaches a mechanical shaker platform being used to provide agitation during the thawing. However, there is no disclosure, teaching, nor suggestion of a container holding biopharmaceutical solution being rolled from a first position to a second position. Further, there is no teaching, disclosure, nor suggestion of a container holding a biopharmaceutical solution being rolled a distance from the second position toward the first position. Thus, because the mechanical shaker platform disclosed in Wisniewski and Wu does not roll from one position to another position nor does it roll a distance from a second position toward a first position, it is respectfully submitted that the features of claim 18 are not taught nor suggested by the cited reference. Accordingly, it is respectfully submitted that claim 18 is not obvious over the Wisniewski and Wu reference. Further, the dependent claims are believed not to be obvious over these references for these reasons and for their own additional features.

Also, the Office Action alleges claims 2, 3, 6-9, and 18 to be obvious over the Wisniewski and Wu article in view of Baldus. As described previously, it is respectfully submitted that Baldus is non-analogous art. Even if it was an analogous art, Baldus does not disclose, teach, nor suggest a container holding biopharmaceutical solution being rolled from a first position to a second position nor such a container being rolled a distance from the second position toward the first position.

Claims 2, 3, 6-9, and 18 stand rejected under 35 U.S.C. § 103(a) as being obvious over the 1992 Wisniewski and Wu article in view of Schmidt (U.S. Patent No. 5,999,701).

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Schmidt is alleged to disclose an oscillator operating at a frequency in a range which would have rendered the range recited in claim 18 as presented in the last Response obvious. As noted above, the recitation of the frequency of the oscillatory motion has been deleted from claim 18. Further, there is no disclosure, teaching, nor suggestion in Schmidt of a biopharmaceutical solution being held in a container which is rolled from a first position to a second position nor such container being rolled from the second position a distance toward the first position. Thus, it is respectfully submitted that the features of claim 18 are not taught nor suggested by Schmidt and claim 18 is believed to be allowable. The dependent claims are believed to be allowable for these reasons and for their own additional features.

Claims 2, 3, 6-9, and 18 stand rejected under 35 U.S.C. § 103(a) as being obvious over the 1992 Wisniewski and Wu article in view of German reference no. DE 3047784. As noted above, the recitation of the frequency of oscillatory motion has been deleted from claim 18. Further, there does not appear from the figures of the German reference nor Scheiwe et al. (U.S. Patent No.4,473,739), which appears to be related to the German reference, that there is any disclosure, teaching, or suggestion of a container holding biopharmaceutical solution which moves from a first position to a second position nor rolling thereof from the second position toward the first position. Thus, it is respectfully submitted that claim 18 is not obvious over these references and it is believed to be allowable. The dependent claims are believed to be allowable for these reasons and for their own additional features.

Claims 2, 3, 6-9, and 18 stand rejected under 35 U.S.C. § 103(a) as being obvious over the 1992 Wisniewski and Wu article in view of the Quan et al. article entitled "Effects of Vibration on Ice Contact Melting within Rectangular Enclosures". The frequency as previously recited in claim 18 is alleged to be obvious over these references. As noted, the recitation of a frequency of oscillatory motion has been removed from claim 18. Further, these references do not disclose a container holding biopharmaceutical solution which rolls from a first position to a second position nor which rolls from the second position a distance

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toward the first position. Thus, claim 18 is believed to be allowable over these references along with the dependent claims for the reasons mentioned above.

Claims 2, 6, and 18 stand rejected as being obvious over the Wisniewski and Wu article in view of Peppers. As noted in the previous Response, it is respectfully submitted that Peppers is not in an analogous art. Even if Peppers was in an analogous art, it does not disclose, teach, nor suggest the subject matter recited in the claims of the present application. Specifically, the Office Action alleges that the frequencies recited in claim 18 as presented in the previous response would be obvious based on a combination of these references. As noted, the recitation of frequency of oscillatory motion has been removed from claim 18. Further, these references do not disclose a container holding biopharmaceutical solution being rolled from a first position to a second position nor rolling thereof from the second position a distance toward the first position. Thus, it is respectfully submitted that claim 18 is not obvious over these references and the dependent claims are not obvious for the same reasons and for their own additional features.

New Claims

Claims 19, 20, and 21 have been added to recite subject matter not previously claimed.

CONCLUSION

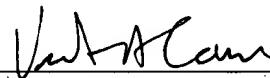
It is believed that the application is in condition for allowance, and such action is respectfully requested.

Attached hereto is a marked up version of the changes made to claim 18. New claims 19-21 have not been duplicated. The attachment is captioned "**Version with markings to show changes made.**"

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If a telephone conference would be of assistance in advancing prosecution of the subject application, Applicant's undersigned attorney invites the Examiner to telephone him at the number provided.

Respectfully submitted,



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"VERSION WITH MARKINGS TO SHOW CHANGES MADE."

18. **(Twice Amended)** A method for thawing a frozen biopharmaceutical solution, the method comprising:

heating the biopharmaceutical solution, when at least a portion of the biopharmaceutical solution is frozen, using a heating element coupled to a container which contains the biopharmaceutical solution; and

inducing oscillatory motion to the biopharmaceutical solution to thaw the at least a portion of the biopharmaceutical solution using an oscillatory driver adapted to be coupled to the biopharmaceutical solution; and

~~wherein a frequency of the oscillatory motion of the oscillatory driver ranges from about 0.01 Hz to less than about 20 Hz.~~

wherein the driver inducing the oscillating motion rolls the container from a first position to a second position and the driver rolls the container a distance from the second position toward the first position.